

REMARKS

Claims 1-3 and 5-13 are pending. Claim 1 is amended. Claims 3 and 4 were previously withdrawn. No new matter is added.

Rejection of Claim 1 under 35 U.S.C. § 112

The Office Action rejects claim 1 under 35 USC § 112, second paragraph, for alleged indefiniteness. Specifically, the Office Action asserts that “[t]here is insufficient antecedent basis for [“said vaccine composition”] in the claim.” Solely in the interest of expediting prosecution of the instant application, claim 1 has been amended to recite “said composition”, for which antecedent basis exists within claim 1. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 1 under 35 USC § 112, second paragraph.

Rejection of Claims 1-11 and 13 under 35 U.S.C. § 102(b)

The Office Action rejects claims 1-11 and 13 under 35 U.S.C. § 102(b) for alleged lack of novelty over Hoo *et al.*, U.S. Patent No. 5,891,432. Specifically, the Office Action alleges that Hoo *et al.* anticipates the instant invention by disclosing a composition comprising “an antigen and a fusion polypeptide [where] the antigen and the fusion polypeptide are bounded and unbounded together.” Applicants respectfully traverse this rejection.

For a prior art reference to anticipate a claimed invention, the prior art must teach **each and every element** of the claimed invention. *Lewmar Marine v. Barient*, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987).

Hoo *et al.* fails to describe a “composition comprising an antigen bearing target and a fusion polypeptide, said fusion polypeptide comprising a first amino acid sequence which can bind to a carbohydrate and a second amino acid sequence comprising a ligand for a cell surface polypeptide of a leukocyte, wherein said composition includes said fusion polypeptide bound to a carbohydrate on said antigen bearing target and includes said polypeptide **which is not bound to said antigen bearing target**,” as the instant claims require. Indeed, Applicants respectfully submit that the Office Action fundamentally misstates the disclosure of Hoo *et al.*, as Hoo *et al.*

in no way discloses, or even suggests, a composition which comprises fusion polypeptide "**which is not bound to [an] antigen bearing target**," as the instant claims require. In fact, claim 1 of Hoo *et al.*, which is specifically alleged in the Office Action to support "the fusion polypeptide are bounded and unbounded together" explicitly requires that the fusion polypeptide be "membrane bound", *i.e.*, bound to the cell, *i.e.*, the antigen. There is no disclosure in Hoo *et al.* whatsoever of fusion polypeptide which is **not bound to an antigen bearing target** (*e.g.*, the cell). Nor does Claim 12 of Hoo *et al.*, which the Office Action also specifically cites to support unbounded fusion polypeptide, or the remainder of the Hoo *et al.* reference correct this defect.

In contrast, the presence of fusion polypeptide which is **not bound to an antigen bearing target** (*e.g.*, a cell) is an indispensable element of the instant claims. At least in view of the presence of this element, the instant claims are conclusively distinguished over the Hoo *et al.* reference. Thus, Hoo *et al.* fails to anticipate the claimed invention, as it fails to disclose or suggest each and every element of the instant claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-11 and 13 under 35 U.S.C. § 102(b).

Rejection of Claims 1 and 12 under 35 U.S.C. § 103(a)

The Office Action rejects claims 1 and 12 under U.S.C. § 103(a) over Hoo *et al.* in view of Faulkner *et al.* (*Vaccine* 21: 932-39). Specifically, the Office Action alleges that Faulkner *et al.* teaches the use of a lectin, influenza hemagglutinin, which binds to sialic acid, and that it would have been obvious to "use one lectin as an alternative for another lectin." The Office Action further alleges that one of ordinary skill in the art would have been motivated to do so to facilitate the delivery of the composition of Hoo *et al.* Applicants traverse this rejection.

The Office Action has failed to establish a *prima facie* case of obviousness under the requirements of 35 U.S.C. § 103(a). To establish a *prima facie* case of obviousness, the Examiner must establish that the prior art included each element claimed (M.P.E.P. 2143). In addition, "[a] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known

in the prior art." *KSR International Co. v. Teleflex Inc.* 167 L. Ed. 2d 705, 712. Under section 103, "[b]oth the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure" (*Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.* 927 F.2d 1200, 1207, 18 USPQ2d 1016 (Fed. Cir. 1991), quoting *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed Cir. 1988)).

The combination of Hoo *et al.* and Faulkner *et al.* fails to support the rejection of the claims as obvious. First, as set forth above, Hoo *et al.* fails to disclose or suggest a "composition comprising an antigen bearing target and a fusion polypeptide, said fusion polypeptide comprising a first amino acid sequence which can bind to a carbohydrate and a second amino acid sequence comprising a ligand for a cell surface polypeptide of a leukocyte, wherein said composition includes said fusion polypeptide bound to a carbohydrate on said antigen bearing target and includes said polypeptide **which is not bound to said antigen bearing target**," as the instant claims require. Faulkner *et al.* does not cure this defect. Rather, Faulkner *et al.* discloses a fusion polypeptide which comprises a peptide antigen, but does not teach a composition in which that fusion polypeptide is admixed or otherwise combined—whether in bound form, unbound form, or both—with a second antigen.

Moreover, contrary to the assertion in the Office Action, Faulkner *et al.* does not disclose a lectin at all. As one of ordinary skill in the art would recognize, the extremely short hemagglutinin (HA) peptides disclosed in Faulkner *et al.* cannot bind carbohydrate. Aytay and Schulze (1991, *J. Virology* 65: 3022) teach that the carbohydrate binding domain of HA consists of a shallow pocket present on the distal end of the HA1 subunit. The specific sialic acid binding region has also been identified. Weis *et al.* (1988, *Nature* 333: 426) teach that the binding site is a depression, the bottom of which is formed by the phenolic hydroxyl of Tyr 98 and the aromatic ring of Trp 153, that Glu 190 and Leu 194 project down to form a short alpha-helix to define the rear of the site with His 183 and Thr 155, and that residues 134 to 138 form the 'right' side of the site and residues 224 to 228 form the 'left' side. Moreover, various mutagenesis studies have been carried out to determine which residues in the binding pocket are critical for SA binding (see, e.g., Nobusawa *et al.*, 2000, *Virology*, 278: 587; Martin *et al.*, 1998, *Virology* 241:101; Nobusawa and Nakajima, 1988, *Virology* 167: 8;

and Rogers *et al.*, 1983, *Nature* 304: 76). It is thus known in the art that amino acids 98, 134-138, 153, 155, 183, 190, 194, and 224-228 of HA are critical for sialic acid binding.

The short HA peptide disclosed in Faulkner *et al.* has the sequence SFERFEIFPK and spans amino acid positions 110-119. Faulkner *et al.* also discloses a second HA peptide spanning positions 94-131. The peptides disclosed in Faulkner *et al.* therefore omit residues involved in and critical for carbohydrate binding. Thus, these peptides could not bind carbohydrate, and neither Faulkner *et al.* nor the Office Action provides any evidence that they can do so.

Nor does Hoo *et al.* disclose lectins. Indeed, none of the fusion polypeptides disclosed in Hoo *et al.* includes a carbohydrate binding domain.

Thus, even if combined, Hoo *et al.* and Faulkner *et al.* do not provide all of the elements of the rejected claims.

Applicants also respectfully submit that there would have been no motivation for the skilled artisan to combine the Hoo *et al.* and Faulkner *et al.* references. Because neither reference actually discloses lectins as part of fusion polypeptides, the allegation that it would have been obvious to "use one lectin as an alternative for another lectin" is rendered moot. Furthermore, the two references disclose fundamentally different things: Hoo *et al.* discloses use of membrane-bound fusion proteins to improve cell-based vaccines, whereas Faulkner *et al.* discloses a soluble fusion protein to deliver a small peptide epitope (without a cell). Thus, it is unclear how the disclosure of Faulkner *et al.* could facilitate the delivery of the composition of Hoo *et al.*

In view of all of the above, Applicants assert that the combination of Hoo *et al.* and Faulkner *et al.* references fails to obviate the instant claims. Specifically, the combination of Hoo *et al.* and Faulkner *et al.* references fails to disclose or suggest a "composition comprising an antigen bearing target and a fusion polypeptide, said fusion polypeptide comprising a first amino acid sequence which can bind to a carbohydrate and a second amino acid sequence comprising a ligand for a cell surface polypeptide of a leukocyte, wherein said composition includes said fusion polypeptide bound to a carbohydrate on said antigen bearing target and includes said polypeptide **which is not bound to said antigen bearing target,**" as the instant claims require.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1 and 12 under U.S.C. § 103(a).

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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